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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,841	11/28/2000	Kenneth H. Grabstein	66033-10/2811-H	6624

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,841	GRABSTEIN ET AL.	
	Examiner	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-30,34,35 and 41-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-30, 34-35, 41-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-19, 31-33, 36-40 have been canceled. Amended claims 20, 28, 34 (6/29/04) and claims 21-27, 29-30, 35, 41-45 (claims 41-45 contain the subject matter of previously canceled claims 36-40) are under consideration.

2. Receipt of applicant's arguments and amendments filed on 6/29/04is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 6/29/04:

(i) the objection to the title of the invention;

(ii) the objections to the specification with respect to the status of the prior applications and the ATCC address; and

(iii) the rejection of claims 20-30 and 34-35, under 35 U.S.C. 112, second paragraph. However, Applicants arguments with respect to these claims are rendered moot in light of the new ground of rejection.

4. Applicant's arguments filed on 6/29/04 have been fully considered and were persuasive in part. The previous issues as well as the new issues are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-35 USC § 112, first paragraph

6. Claims 20-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

This rejection is maintained for reasons of record set forth at pages 2-3 of the previous Office action of 3/31/2004.

Applicants argue that on page 26, line 27, the specification recites "12 nucleotides" and therefore the recitation of "at least 12 nucleotides" is not new matter. However, contrary to Applicants' arguments, the limitation in claim 20 recites "at least 12 contiguous nucleotides" while the specification on page 26, line 27, recites "about 12 nucleotides". Therefore, the recitation of "at least 12 contiguous nucleotides" is new matter in the claim.

New 35 USC § 112, first paragraph rejections

7. Claims 20-30, 34-35, 41-45 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for isolated nucleic acid molecules of claim 20 (a), (b), (c), or (d) that specifically bind to the complement of the polynucleotide of SEQ ID NO:1, does not reasonably provide enablement for isolated nucleic acid molecules of claim 20 (a), (b), (c), or (d) "capable of" specifically binding to the complement of the polynucleotide of SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification is non-enabling for isolated nucleic acid molecules that do not specifically bind and are only capable of if further modified such that they can then bind, because applicants have not taught how to further modify a nucleic acid molecule such that it can bind to its target. It has been held that an element is "capable of" performing a function is not a positive limitation but only requires the ability to perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. This rejection also applies to claim 41, which recites "capable of hybridizing".

8. Claims 41-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses a nucleic acid comprising a nucleotide sequence set forth in SEQ ID NO:1 or 4. These nucleic acids meet the written description and enablement provisions of 35 U.S.C. 112, first paragraph. However, the claims are directed to encompass oligonucleotides of at least 14 nucleotides in length "capable of hybridizing under conditions of moderate stringency". None of these oligonucleotide molecules meet the written description provision of 35 USC 112, first paragraph.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, makes clear that applicant must convey with reasonable clarity to those skilled in the art, as the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry whatever is now claimed (see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. (See Vas-Cath Inc. V. Mahurkar, page 1116.).

With the exception of a nucleic acid comprising SEQ ID NO:1 or 4, the skilled artisan cannot envision the detailed chemical structure of the encompassed oligonucleotides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that is part of the invention and reference to a potential method for isolating it, the nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd. 18 USPQ 2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird 30 USPQ 2d 1481, 1483. In *Fiddes*,

claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated oligonucleotides comprising the nucleotide sequence set forth in SEQ ID NO: 1 or 4, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Furthermore, with respect to claim 41 there is no structure/function relationship recited in the claim since the only function recited for the oligonucleotide is that it is "capable of hybridizing" and there are no constraints on the sequence. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

However, no disclosure, beyond nucleic acids comprising SEQ ID NO:1 and 4, is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63,

Number 114, pages 32639-32645. Therefore only an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:1 or 4 and equivalent degenerative codon sequences thereof, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

Claim rejections-35 USC § 112, second paragraph

9. Claims 41-45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 recites the limitation "moderate stringency". In the specification, page 10, lines 1-5, Applicants disclose:

Moderate stringency conditions, as defined herein and as known to those skilled in the art, refer to conditions described in, for example, Sambrook et a1., supra, Vol. 2, pp. 8.46-8.49 and 9.47-9.55. Conditions of moderate stringency, as defined by Sambrook et al. include, for example, overnight hybridization and post-hybridization washes at 55C, 5 x SSC, 0.5% SDS.

Therefore, contrary to Applicants' arguments, the stringency conditions recited in the specification are exemplary and renders the claim indefinite. Furthermore, some nucleic acids which might hybridize under conditions of moderate stringency, for example, would fail to hybridize at all under conditions of high stringency. The metes and bounds of the claim thus cannot be ascertained.

Claims 41-45 are rejected as vague and indefinite insofar as they depend on claim 41 for the rejected limitation.

Claim rejections-35 USC § 102

10. Claims 20-22, 26-27, 34-35, 41-45 are rejected under 35 USC 102(b) as being anticipated by Smith et al. (1991).

This rejection is maintained for reasons of record set forth at page 5 of the previous Office action of 3/31/2004.

Applicants argue that claim 20 as amended is supported by the specification (page 27, lines 24-28) and sequences, which are highly specific for the target sequences should not form duplexes with other regions. However, contrary to Applicants arguments, claim 20 recites "capable of binding" and claim 41 recites "capable of hybridizing", which limitations encompass nucleic acid molecules that need not necessarily bind or hybridize. The prior art nucleic acid molecule will bind to the claimed nucleic acid molecules. Applicants have recognized that 12 contiguous nucleotides can hybridize or bind to another nucleic acid molecule and have therefore claimed a 12 nucleotide molecule in claim 20. If Applicants exclude the 12 nucleotides of the prior art that are 100% identical to nucleotides 1-13 of SEQ ID NO:1 of the instant application, then all other 12 nucleotide molecules are excluded. It is suggested that Applicants delete the recitation of "12 contiguous nucleotides" and the "capable of binding/hybridizing" limitation, to obviate this rejection.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
August 3, 2004